

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. 98 N-0182]

**List of Bulk Drug Substances That May Be Used in Pharmacy Compounding;
Preliminary Draft Proposed Rule; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of preliminary draft proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations identifying the bulk drug substances that may be used in pharmacy compounding under the exemptions provided by the Federal Food, Drug, and Cosmetic Act (the act) even though they are neither the subject of a current United States Pharmacopoeia (USP) or National Formulary (NF) monograph nor a component of an FDA approved drug. FDA's development and publication of this bulk drug list is required by the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This preliminary draft of the proposed rule is being made available to allow full discussion of its contents at the Pharmacy Compounding Advisory Committee meeting to be held on October 14, 15, and 16, 1998. FDA is requesting comments concerning the preliminary draft of the proposed rule.

DATES: Submit written comments on or before October 30, 1998.

ADDRESSES: A copy of the preliminary draft proposed rule will be on display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit requests for copies of the preliminary draft proposed rule from the Drug Information Branch (HFD-210), Food and Drug Administration, 5600 Fishers Lane,

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Display Date	10.13.98
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Certifier	A. W. H. S. Day

Rockville, MD 20857, 301-8274573, and the Center for Drug Evaluation and Research's Fax-on-Demand system at 301-827-0577 or 800-342-2722. An electronic version of the preliminary draft proposed rule is available via the Internet at 'http: //www.fda.gov/cder/fdama' under the subject 'Pharmacy Compounding. "

FOR FURTHER INFORMATION CONTACT: Robert J. Tonelli, Center for Drug Evaluation and Research (HFD-332), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-7295.

SUPPLEMENTARY INFORMATION:

I. Background

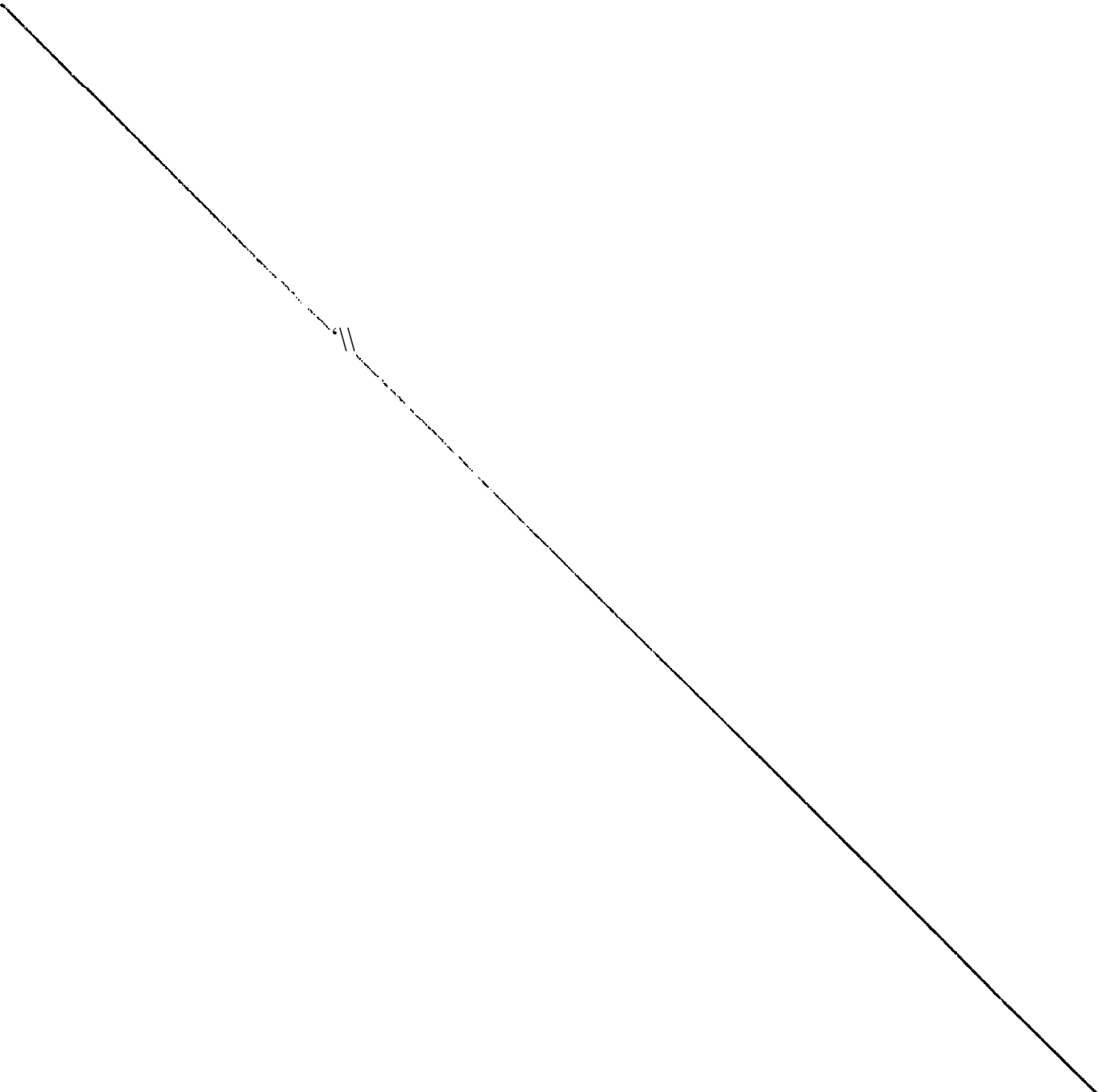
On November 21, 1997, the President signed the Modernization Act (Pub. L. 105-115) into law. Section 127 of the Modernization Act, which adds section 503A to the act (21 U.S.C. 353a), clarifies the status of pharmacy compounding under Federal law.

Section 503A(d)(1) of the act requires that, unless good cause is shown, FDA convene and consult with an advisory committee on compounding before issuing regulations listing bulk drug substances that may be used in pharmacy compounding. The Pharmacy Compounding Advisory Committee was established by a final rule published in the **Federal Register** of March 10, 1998 (63 FR 11596). A meeting of the advisory committee to discuss, among other things, the list of bulk drug substances that may be used in pharmacy compounding was announced in the **Federal Register** of September 4, 1998 (63 FR 47301). The meeting will be held on October 14, 15, and 16, 1998.

Under 21 **CFR** 10.40(f)(4) and 10.80(b)(2), FDA has decided to make available to the public a preliminary draft proposed rule identifying the bulk drug substances that may be used in pharmacy compounding under the exemptions provided by the act even though they are neither the subject of a current USP or NF monograph nor a component of an FDA approved drug. This preliminary draft proposed rule is being made available to facilitate a full and open discussion at the advisory committee meeting of the list of bulk drug substances that may be used in pharmacy compounding.

II. Request for Comments

Interested persons may, on or before October **30, 1998**, submit to the Dockets Management Branch (address above) written comments regarding this preliminary draft proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this



document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

(Authority: 21 U.S.C. 321 *et seq.*)

Dated: October 7, 1998

October 7, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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